No. 98-1152

In The

Supreme Court of the United States

October Term, 1998

FOOD AND DRUG ADMINISTRATION, et al.,

Petitioners,

v.

BROWN AND WILLIAMSON TOBACCO CORP., et al.,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fourth Circuit

BRIEF OF THE STATES OF MINNESOTA, ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, FLORIDA, HAWAII, IDAHO, ILLINOIS, INDIANA, IOWA, KANSAS, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MISSISSIPPI, MISSOURI, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH DAKOTA, OHIO, OKLAHOMA, OREGON, PENNSYLVANIA, RHODE ISLAND, SOUTH DAKOTA, TEXAS, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA AND WISCONSIN AS AMICI CURIAE IN SUPPORT OF PETITIONERS

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INTEREST OF THE AMICI

The thirty-nine Amici States submit this brief in support of the petition of the U.S. Food and Drug Administration (FDA) for a writ of certiorari. The States have an overwhelming interest in the vitally important question of whether the FDA has jurisdiction to regulate tobacco products under the Federal Food, Drug and Cosmetic Act (FDCA).

This Court has often recognized the States' responsibility for promoting the health, safety and welfare of their citizens. "Throughout our history the several States have exercised their police powers to protect the health and safety of their citizens. . . . [T]he 'states traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.' " *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (citations omitted); *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1954) ("[A] state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power.")

Tobacco products dramatically affect the health, safety and welfare of the citizens of the Amici States. Tobacco use is the leading cause of preventable death in the United States. Tobacco products cause millions to suffer from smoking-related illnesses, including respiratory diseases, cardiovascular diseases, and cancer. In addition to the human toll, smoking imposes a huge economic burden on the states, both in terms of health care costs and in lost earnings and productivity. Despite

the overwhelming evidence of harm, tobacco use among young people is on the rise.

The States have a substantial interest in limiting access by young people[1] to tobacco products and in reducing the widespread death and disease caused by nicotine addiction, cigarettes and smokeless tobacco. The FDA's role in regulating these dangerous products is an essential complement to the State's efforts. The FDA regulations at issue in this case are fully authorized by law and perform a critical function in the comprehensive federal, state and local effort needed to prevent children from using and becoming addicted to the drug nicotine.

SUMMARY OF ARGUMENT

The FDA's petition for a writ of certiorari should be granted for three reasons. First, this case is of enormous public importance. The regulations at issue address the number one preventable public health issue of our time. Although the recent settlements between the States and the tobacco manufacturers make important strides, the FDA's regulations address matters that cannot be effectively addressed by the States alone. The Fourth Circuit's decision that the FDA lacks the authority to regulate tobacco products as drug delivery devices impedes the

[1] Because of the evidence that most tobacco-related addiction begins in childhood, FDA directed its initial regulations to reducing the use of tobacco products by young people.

FDA from joining the States in fully addressing this significant public health problem.

Second, the Fourth Circuit's decision misapplies important, well-settled principles of administrative law that require deference to the FDA's judgment and permit the FDA to determine which products fit within the broad statutory framework for regulation of "drugs" and "devices" under the FDCA. The circuit court substituted its judgment for that of the FDA, and essentially ignored the compelling – but until recently secret – evidence from the tobacco industry's own files relied upon by the FDA in asserting jurisdiction over tobacco products.

This evidence overwhelmingly shows, as Judge Hall found in his dissent, "that the companies have known about the addictive qualities of their products for years and that cigarettes are deliberately manipulated to create and sustain addiction to nicotine." Pet. A. 58a (Hall, J., dissenting).[2] Additional evidence the States obtained through their own litigation further exposed the industry's knowledge that its products fall squarely within the FDA's jurisdiction. Again, in the words of Judge Hall's dissent, "[t]he strength of nicotine's addictive qualities, the extent of the health problems created by tobacco products, and the complicity of the manufacturers bring us to a different place than we have been before." Pet. A. 59a.

Finally, the Fourth Circuit's decision fundamentally misconstrues the relationship between the States and the

[2] Reference is to the Appendix To Petition For Writ of Certiorari.

federal government. The States have enacted laws to prevent young people from using tobacco. The States also have an important role to play in implementing the Alcohol, Drug Abuse and Mental Health Administration Reorganization Act enacted by Congress in 1992. However, the federal government, through the FDA, has a vital role to play in both limiting youth access to tobacco and restricting advertising that appeals to young people. Contrary to the circuit court's conclusion, FDA regulation of tobacco products is fully authorized by the FDCA and performs a critical function in the comprehensive effort that is needed to address this important public health issue.

REASONS FOR GRANTING THE PETITION

I. THIS IS A CASE OF EXCEPTIONAL IMPORTANCE TO THE PUBLIC HEALTH AND OUR NATION'S CHILDREN.

This Court should grant review because of the exceptional public importance of this case. Every day, 3,000 American children start using tobacco regularly. Fully one-third of those who continue using tobacco products will suffer from painful, debilitating tobacco-related diseases including lung cancer, oral cancer, throat cancer, bladder cancer, cancer of the esophagus, cancer of the pancreas, heart disease, and chronic obstructive pulmonary disease. Millions of people in this country suffer from these diseases, and die prematurely, because they became addicted to the drug nicotine in the tobacco products they began to use as children. Over 400,000 individuals die each year from tobacco-related diseases. This is the

equivalent of three fully loaded 747s crashing every day, 365 days a year, with no survivors.

The Amici States confront the magnitude of the human and economic consequences of tobacco use each and every day. These consequences are enormous and, without FDA regulation, will likely grow even larger. The Amici States have all enacted laws designed to prevent young people from using tobacco products. Despite these efforts, tobacco use by young people is on the rise.

Over the past several years, more than forty State Attorneys General pursued their own litigation against the tobacco industry. Each of the States brought claims under its own state laws, in its own state courts. These lawsuits alleged a decades-long conspiracy by the tobacco industry to conceal the deadly and addictive nature of their products. The recent agreements between the States and the nation's five largest tobacco companies settling these cases achieve important advances, but do not diminish the importance of this case.[3] These agreements do not address the central issue here, *i.e.* whether nicotine and tobacco products are subject to regulation by the FDA. Moreover the settlement is binding only on the signatories to the agreements. Thousands of retailers and other entities involved in the sale and distribution of

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[3] The terms of the recent settlement between forty-six states, five territories and the District of Columbia and the nation's five largest tobacco companies are contained on the website maintained by the National Association of Attorneys General. *See* http://www.naag.org/tob2.htm. The States of Minnesota, Florida, Texas and Mississippi had previously settled their claims against the tobacco companies.

tobacco products are not bound by the settlements. Thus, while the agreements make significant strides, the FDA rules at issue here cover important ground that the settlements with the States did not and could not address.

The circuit court does not dispute the harm caused by tobacco products; indeed, the court contends that the harm is so great, that the FDCA would require the FDA to ban the products as inherently unsafe and dangerous, rather than simply regulating them. Pet. A. 29a. The absurd conclusion that a drug is so dangerous that it cannot be regulated at all must be reviewed by this Court. The issues of Congressional intent, FDA authority, and the harms that flow from nicotine addiction are simply too important to the States, to the public health, and to the well-being of our nation's children.

II. WELL-ESTABLISHED LAW PERMITS THE FDA TO CHANGE ITS POSITION AND REGULATE TOBACCO PRODUCTS, PARTICULARLY WHERE THERE IS NEW EVIDENCE FROM THE INDUSTRY'S OWN FILES SHOWING THAT NICOTINE IS AN ADDICTIVE DRUG AND CIGARETTES ARE DRUG DELIVERY DEVICES.

The Fourth Circuit's decision should also be reviewed because its logic runs contrary to well-established administrative law, which requires deference to agency judgments and which permits the FDA to change its position on whether a product should be regulated based upon new information or if it has other sound reasons for doing so. The district court properly applied these well-established principles. Pet. A. 90a-92a.

It is axiomatic that the FDA has the authority under the FDCA to regulate drugs[4] and devices.[5] It is also beyond dispute that Congress has delegated to the FDA the responsibility of determining, based on the evidence, which specific products meet the statutory definitions. The FDA properly determined that tobacco products fall within the statutory standards for both "drug" and "device," and are therefore subject to regulation under the FDCA. The FDA's jurisdictional determination was based on an overwhelming factual record demonstrating that nicotine is a drug, and that the tobacco manufacturers deliberately design and market their products to promote the addictive properties of nicotine. *See, e.g., Jurisdictional Determination*, 61 Fed. Reg. 44,619, 44,854-994 (1996); *Jurisdictional Analysis*, 60 Fed. Reg. 41,453, 41,583-784 (1995). As the FDA explained in the rulemaking record, "[t]he quality, quantity, and scope of the evidence available to FDA today is far greater than any other time when FDA has considered regulation of cigarettes and smokeless tobacco products." 60 Fed. Reg. at 41,464 n.1.

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[4] The term "drug" is defined to include not only "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," but also "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1).

[5] The term "device" includes "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended to affect the structure or any function of the body of man or other animals . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

The FDA's well-reasoned and extensively documented basis for regulating tobacco products is entitled to deference. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984) ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer"). Moreover, that the FDA chose not to regulate nicotine sooner does not preclude it from doing so now. "An initial agency interpretation is not instantly carved in stone. On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis." *Id.* at 863-64; *Rust v. Sullivan*, 500 U.S. 173, 186-87 (1991) ("An agency is not required 'to establish rules of conduct to last forever' . . . but rather 'must be given ample latitude to adapt its rules and policies to the demands of changing circumstances.' " (citations omitted)).

In fact, the FDA's regulation of tobacco products is long overdue. The change in the FDA's position concerning regulation of the drug nicotine and the drug delivery device of tobacco products is based in large part upon compelling new evidence from the tobacco industry's heretofore secret internal files. If the government had known earlier what the industry knew and conspired to conceal for years – about the addictiveness of nicotine, about the industry's efforts to manipulate levels of nicotine, and about the industry's efforts to target young people – the FDA may well have acted much sooner.

The suits by the Amici States against the tobacco industry have resulted in the production of even more previously secret evidence from the tobacco industry's

own files. Minnesota's case alone produced over 33 million pages of documents in depositories in Minnesota and England, as well as approximately 40,000 more documents over which the industry had claimed an attorney-client privilege.[6] These documents, the majority of which had not been produced by the industry before, fully confirm the FDA's position that nicotine is a drug; that cigarettes are drug delivery devices; and that the tobacco industry has known and studied for years how to manipulate, and maximize, the impact of nicotine on the addicted smoker. A recently published article in the Journal of the American Medical Association sets forth many representative tobacco industry documents relating to the issues of addiction, cigarette design and nicotine manipulation.[7] The authors conclude, based on their review of thousands of pages of industry documents, that the industry knew for decades of the addictiveness of nicotine and perpetuated that addiction through manipulation of nicotine.[8] Several of the exhibits in Minnesota's trial against the industry, discussed in the JAMA article, illustrate why the Amici States believe so strongly that Supreme Court review of this case is warranted:

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[6] The tobacco manufacturers and tobacco-related organizations that are parties to the recent national settlement with many of the Amici States have agreed to maintain internet document websites accessible through "TobaccoResolution.com" where documents produced in the States' litigation will be accessible to the public.

[7] Richard D. Hurt, M.D. & Channing R. Robertson, Ph.D., *Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial*, 280 JAMA 1173 (1998) ("Hurt & Robertson").

[8] *Id.* at 1180.

- A "CONFIDENTIAL" 1969 memo written to Phillip Morris research director Dr. Helmut Wakeham:

> I would be more cautious in using the pharmic-medical model – do we really want to tout cigarette smoke as a drug? It is, of course, but *there are dangerous F.D.A. implications to having such conceptualization go beyond these walls.*[9]

- A "CONFIDENTIAL" Research Planning Memorandum written in 1972 by Claude E. Teague, Jr., assistant director of research at R.J. Reynolds, entitled "The Nature of the Tobacco Business and the Crucial Role of Nicotine Therein":

> In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products, uniquely, contain and deliver nicotine, a potent drug with a variety of physiological effects. . . . *Thus, a tobacco product is, in essence, a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form.* Our Industry is then based upon design, manufacture and sale of attractive dosage forms of nicotine, and our Company's position in our Industry is determined by our ability to produce dosage forms of nicotine which have more overall value,

[9] *Id.* at 1176 (emphasis added).

> tangible or intangible, to the consumer than those of our competitors.[10]

- A 1972 Phillip Morris memorandum summarizing the discussion at a conference attended by 25 scientists from England, Canada and the United States:

> The majority of conferees would accept the proposition that nicotine is the active constituent of cigarette smoke. . . . The cigarette should be conceived not as a product but as a package. The product is nicotine. Think of the cigarette pack as a storage container for a day's supply of nicotine. . . . Think of the cigarette as a dispenser for a dose unit of nicotine. . . . Think of a puff of smoke as the vehicle of nicotine. . . . Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke.[11]

These documents, and many others like them, underscore the overwhelming record compiled by the FDA in the course of promulgating the administrative rules at issue here. The documents convincingly establish that nicotine is a drug that, in the words of the FDCA, "affects the structure or any function of the body." Moreover, the evidence convincingly demonstrates that the tobacco

[10] *Id.* at 1175 (emphasis added). This document was cited by the FDA in support of its regulation of tobacco products. *See* 60 Fed. Reg. 41,453, 41,617-18 (1995) (quoting from New York Times newspaper report).

[11] Hurt & Robertson, *supra* n. 7 at 1176; 60 Fed. Reg. 41,453, 41,617 (1995).

manufacturers fully intend this result, and deliberately manipulate the nicotine levels in their products to maximize its effect and promote addiction. The FDA properly determined based upon a comprehensive and exhaustive review of the evidence that tobacco products meet the requisite statutory definitions and are subject to regulation under the FDCA. The circuit court's decision failed to give the FDA's judgment the deference that it was entitled to receive. *See Chevron*, 467 U.S. at 844.

The Amici States urge this Court to grant the FDA's petition to review this case to consider the agency's assertion of jurisdiction over tobacco products. The tobacco companies long ago understood that "we are in a nicotine rather than a tobacco industry,"[12] and at least one suggested that it "should learn to look at itself as a drug company rather than as a tobacco company."[13] This Court should review the Fourth Circuit's decision precluding the FDA from responding to new evidence to regulate tobacco products because, in the words of Judge Hall's dissent, "the 'cold hard facts' are now in." Pet. A. 64a.

[12] Hurt & Robertson, *supra* n.7 at 1176.

[13] *Id.*

III. THE FOURTH CIRCUIT'S DECISION FUNDAMENTALLY MISCONSTRUES THE IMPACT OF STATE REGULATION OF TOBACCO PRODUCTS: THE LAW PERMITS, AND THE PROBLEM DEMANDS, A COMPREHENSIVE FEDERAL, STATE AND LOCAL EFFORT.

Finally, this Court should review the Fourth Circuit's decision because the lower court misconceives the relationship between the States and the federal government. The circuit court found that Congress, through the Alcohol, Drug Abuse and Mental Health Administration Reorganization Act of 1992 (ADAMHA amendments), expressed "clear congressional intent that States exercise their traditional police powers and take a primary role in attacking the problem of youth access to tobacco products." Pet. A. 51a. The court concluded that the FDA does not have jurisdiction over tobacco because there is an "inherent conflict" between the FDA's regulations and the primary state regulatory role allegedly established by Congress in the ADAMHA amendments. *Id.*

The circuit court's analysis is flawed for several reasons. First, as the district court and the dissenting judge at the Fourth Circuit properly observed, the ADAMHA amendments merely establish conditions for the receipt of federal funds; they "do not represent an all-encompassing last-word pronouncement of federal policy on underage smoking." Pet. A. 100a, 69a-70a.

Second, even assuming the ADAMHA amendments signal an intent by Congress that States regulate underage tobacco use, the FDA regulations permit continued state enforcement of many laws affecting youth access to tobacco including, for example, restrictions on the sale or

distribution of tobacco products, restrictions on smoking in public places, penalties on underage smokers and age restrictions on persons who sell tobacco. 61 Fed. Reg. 44,396, 44,549 (1996). "An overlap between two regulatory systems does not require wholesale jettisoning of one in favor of the other." Pet. A. 70a (Hall, J., dissenting).

Third, even those state laws which might be preempted could qualify for exemption, thereby further minimizing conflicts. 61 Fed. Reg. 44,396, 44,548-50; 21 U.S.C. § 360k(b). The FDA has stated that its regulations set only a floor for regulation of youth access to tobacco products, and that "[f]ederal cooperation with, and continued reliance upon, innovative and aggressive state and local enforcement efforts is essential." 61 Fed. Reg. at 44,548.

Finally, while the States have done a great deal to address the problems of tobacco use, federal food and drug regulation has co-existed with state regulation for years. Although the States unquestionably play an essential role in regulating matters pertaining to public health and safety, the federal government also has a very significant role. *Medtronic*, 518 U.S. at 475 ("Despite the prominence of the States in matters of public health and safety, in recent decades the Federal Government has played an increasingly significant role in the protection of the health of our people"). The general design of food and drug regulation allows for complementary state and federal jurisdiction. The circuit courts have recognized this complementary jurisdiction in holding that, while the FDCA is important in setting uniform national standards, the act

does not preclude the States from also regulating products subject to FDA authority.[14]

The ADAMHA amendments do not preclude the FDA from regulating nicotine. FDA regulation of tobacco products is no different than FDA regulation of the many other drugs and devices which are, in the language of the FDCA, "intended to affect the structure or function of the body." While tobacco products may be "different from the run-of-the-mine drugs and devices in the FDA's bailiwick," Pet. A. 74a (Hall, J., dissenting),

> the FDCA was broadly worded by design. In an area in which complex new products (and old products, seen in the light of new evidence) pose the potential for grievous harm, Congress deemed it necessary to delegate to an expert – the FDA – the job of monitoring drugs. Cigarettes and smokeless tobacco clearly fit within the literal terms of the FDCA. Absent a showing that following these statutory terms would be absurd or somehow frustrate congressional intent, [the Court is] bound to uphold FDA jurisdiction.

Id. at 70a-71a.

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[14] *See, e.g., Smith v. Pingree*, 651 F.2d 1021, 1025 (5th Cir. 1981) (FDCA does not preempt Florida statute concerning the fitting and selling of hearing aids. "Because the federal requirements did not regulate every aspect of this area, the state had the implied reservation of power to fill out the scheme."); *Pharmaceutical Soc. of State of New York, Inc. v. Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978) (State law not preempted by the FDCA. "The [FDCA] is not so pervasive as to remove the states entirely from the field of drug regulation.").

The FDA's authority to regulate tobacco products is authorized by law, and is a critically important part of the traditional complementary federal and state regulation of matters affecting public health and safety. The FDA access regulations constitute uniform national standards which the States may build upon. Given the magnitude of the problem, the ADAMHA amendments alone are not enough. The amendments address only the issue of youth *access* to tobacco products. More is needed, including advertising and promotion restrictions, restrictions on retailers, and additional educational efforts directed at children. The FDA regulations are an important step in the right direction. When combined with the ADAMHA amendments and other federal laws, current laws at the state and local level, the advances achieved through State litigation against the tobacco industry, and additional efforts to be undertaken in the future, the FDA's regulations will help limit the number of American youth who become addicted to nicotine. Millions of individuals will benefit, both now and in the future.

The Amici States urge this Court to review this case because the Fourth Circuit's decision is contrary to law, and affects the most important public health issue of this generation.

CONCLUSION

For all the foregoing reasons, the thirty-nine Amici States respectfully request that the petition for a writ of certiorari be granted.

Respectfully submitted,

March, 1999

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